UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CLEVELAND BAKERS AND TEAMSTERS HEALTH & WELFARE FUND, individually and on behalf of others similarly situated,	
Plaintiff,	
v.	**Civil Action No. 23-12575-FDS**
AMAG PHARMACEUTICALS, INC.; COVIS GROUP S.À.R.L.; and COVIS PHARMA GMBH,	
Defendants.	

MEMORANDUM AND ORDER ON
DEFENDANTS' MOTIONS TO DISMISS

SAYLOR, C.J.

This is an action seeking to recover allegedly inflated health-care costs arising out of the marketing and labeling of Makena, a drug designed to reduce the risk of preterm birth. The Cleveland Bakers and Teamsters Health & Welfare Fund provides health and welfare benefits for members of two Cleveland-area unions. Defendants AMAG Pharmaceuticals, Inc.; Covis Group S.à.r.l.; and Covis Pharma GmbH are related entities that develop, market, and sell pharmaceuticals, including Makena. The Food and Drug Administration ("FDA") approved Makena in 2011 but rescinded its approval in 2023.

In substance, plaintiff challenges how defendants marketed Makena from 2019 to 2023. According to the complaint, defendants responded to a study demonstrating that Makena was not effective for its only approved use by continuing to promote the drug and attempting to maintain its FDA approval. The complaint alleges 43 counts: a claim for violation of the civil provisions

of the Racketeer Influenced and Corrupt Organizations ("RICO") statute, 18 U.S.C. § 1962(c) (Count 1); a claim for RICO conspiracy, 18 U.S.C § 1962(d) (Count 2); a claim for unjust enrichment (Count 3); consumer-protection claims under Ohio law on behalf of a subclass of Ohio plaintiffs (Counts 4 and 5); and consumer-protection claims on behalf of a subclass of plaintiffs under the laws of 36 states, including Ohio (Counts 5 - 43).[1]

All defendants have moved to dismiss all counts under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted. Covis Group S.à.r.l. and Covis Pharma GmbH have also moved to dismiss all claims against them under Fed. R. Civ. P. 12(b)(2) for lack of personal jurisdiction. In response, plaintiff has moved for jurisdictional discovery.

For the reasons described below, defendants' motions to dismiss for failure to state a claim will be granted as to all counts. The motions of the Covis defendants to dismiss for lack of personal jurisdiction and plaintiff's motion for jurisdictional discovery will be denied as moot.

I. Background

A. Regulatory Background

1. Approval and Labeling Requirements Generally

Under federal law, a drug company may not market or sell a new pharmaceutical drug without the approval of the Food and Drug Administration. *See* 21 U.S.C. § 355(a). To obtain that approval, the company (which is referred to as the "sponsor") must submit a New Drug Application ("NDA") to the FDA. *Id.* An NDA must provide comprehensive information about the drug, including its formulation, the proposed labeling, and scientific data about its safety and efficacy. *See* 21 U.S.C. §§ 355(b)(1)(A)(i), (iii), (vi); 21 C.F.R. §§ 314.50(d)(5)(viii), 201.57(a).

[1] Count Four of the complaint is mistakenly designated "Count Three," and the subsequent numbering is accordingly off by one. The Court will refer to counts by their ordinal place in the complaint, rather than by the actual numbering.

The FDA approval process is "onerous and lengthy." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013). The FDA will approve a drug only if the NDA demonstrates that the drug (1) the drug is "safe for use," (2) there is "substantial evidence that the drug will have the effect it purports or is represented to have," and (3) it is accompanied by labeling that is neither "false [n]or misleading in any particular." 21 U.S.C. § 355(c)(1)(A), (d).

In certain circumstances, the FDA may grant an NDA using an accelerated approval pathway. *See* 21 C.F.R. § 314.510. That pathway is available only for drugs that treat serious or life-threatening illnesses and that are meaningfully superior for patients than existing treatments. 21 C.F.R. § 314.500. Accelerated approval still requires that there be "substantial evidence" that the new drug is effective for its intended use, but that evidence can be established using results that are reasonable proxies, rather than direct measures, of clinical benefit. 21 C.F.R. § 314.510. Drugs approved using the accelerated pathway must verify their clinical benefit over time through post-marketing studies. *See id.*

The FDA not only approves the drug and its intended use; it also approves the exact text of the drug's label. *See* 21 U.S.C. § 355; *Wyeth v. Levine*, 555 U.S. 555, 568 (2009). With one exception, described below, the sponsor may not alter the label in any respect without the approval of the FDA. *See Wyeth*, 555 U.S. at 568.

2. <u>The Process for Changing Labels</u>

After approving a drug, the FDA retains the authority to require changes to the label to reflect new information concerning its safety and efficacy. 21 U.S.C. § 355(o)(4) ("If the Secretary becomes aware of new information, including any new safety information . . ., that the Secretary determines should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person . . . ."). Nonetheless, a "central premise of federal drug regulation

[is] that the manufacturer bears responsibility for the content of its label at all times." *Wyeth*, 555 U.S. at 570-71. The manufacturer is "charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 571.

Accordingly, when a drug, its process, or its production changes in a way that makes the FDA-approved labeling inadequate, the manufacturer must seek a revision to its labeling. *See* 21 C.F.R. § 314.70(b)(1), (c)(1). There are two ways a manufacturer can change the warnings on a drug label. *See In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 37 (1st Cir. 2015). Both methods ultimately require FDA approval of a supplemental new drug application ("sNDA"). *See* 21 C.F.R. § 314.70(b), (c).

First, a manufacturer can file a "Prior Approval Supplement" ("PAS") requesting revisions to the label. *See* 21 C.F.R. § 314.70(b). That process requires FDA approval before implementation. A drug manufacturer may always file a PAS, but in some circumstances—those that implement "major" changes—the manufacturer must use the PAS process. *See* 21 C.F.R. § 314.70(b). PAS proposals cannot go into effect until the FDA approves them. *See id.*

Second, a manufacturer can file a "changes being effected" ("CBE") supplement instead of a PAS. *See* 21 C.F.R. § 314.70(b). In contrast to the PAS process, a CBE supplement allows the manufacturer to implement some types of proposed changes as soon as the FDA receives its application, and other types 30 days afterward. *See* 21 C.F.R. § 314.70(c)(4), (c)(6). If the FDA ultimately rejects a CBE supplement, the manufacturer must stop distributing the drug with the new labeling. *See* 21 C.F.R. § 314.70(c)(7).

Both CBE and PAS applications are subject to FDA approval. *See* 21 C.F.R. § 314.70(b), (c)(7). The FDA must reject either type of application if the proposed labeling change is false or misleading, or if it does "not comply with the requirements for labels and

labeling" for prescription drugs. 21 C.F.R. § 314.125(b)(6). If the FDA rejects a supplement, it will send the applicant a "complete response letter," which "will describe all of the specific deficiencies that the agency has identified." 21 C.F.R. § 314.110(a).

B. Factual Background

The facts are set forth as alleged in the amended complaint. Facts derived from the briefing and its exhibits are included for clarity and completeness, and only to the extent that they are uncontested.

1. The Parties

The Cleveland Bakers and Teamsters Health & Welfare Fund is an employee benefit fund that provides health and welfare benefits for members of two Cleveland-area unions. (Am. Compl. ¶ 17).

AMAG Pharmaceuticals, Inc. ("AMAG") is a Delaware corporation with a principal place of business in Berkeley Heights, New Jersey. (*Id.* ¶ 18). Prior to 2020, AMAG's principal place of business was in Waltham, Massachusetts, where it still maintains offices. (*Id.*) AMAG marketed and owned the rights to Makena during part of the period at issue in this case. (*Id.*).

Covis Group S.à.r.l. is a private company organized under the laws of Luxembourg and with a principal place of business in Luxembourg. (ECF 50 at 5; ECF 51). It is a holding company whose corporate parents are also private companies organized under the laws of Luxembourg. (ECF 50 at 5; ECF 51). Covis Group S.à.r.l. alleges that it has been sued in error, because it "has no officers or employees of its own" and it has "never owned the rights to Makena and never had any involvement in the manufacture, sale, or marketing of that product." (ECF 50 at 5).

Covis Pharma GmbH is a private company organized under the laws of Switzerland and with a principal place of business in Zug, Switzerland. (ECF 53 at 5; ECF 54). It is a wholly-

owned subsidiary of Covis Group S.à.r.l. (ECF 54). Covis Pharma GmbH currently owns the rights to Makena, and was responsible for regulatory communication and compliance related to Makena during part of the period at issue in this case. (ECF 53 at 5).

2. Makena's Regulatory History

In 2011, the FDA issued an accelerated approval of Makena, a series of hydroxyprogesterone caproate injections used to reduce the risk of preterm birth. (Am. Compl. ¶ 29, 51). The accelerated approval for Makena was based, in part, on a clinical trial indicating that it substantially reduced the rate of recurrent pre-term delivery among high-risk women. (Am. Compl. ¶ 35, 45). However, as with all accelerated approvals, a post-marketing study was required to verify Makena's clinical benefit. (*Id.* ¶ 21, 41).

In 2014, AMAG acquired Lumara, the company that launched Makena. (*Id.* ¶ 49, 51, 59, 60). After the acquisition, AMAG owned the rights to Makena, and became responsible for complying with FDA regulations and corresponding with the FDA about Makena. (*Id.* ¶ 18).

In March 2019, AMAG publicized the results of the post-marketing verification study of Makena. (Am. Compl. ¶ 124). According to that study, called the "PROLONG" study, there was no statistically significant improvement in clinical outcomes associated with the use of Makena. (*Id.*).

In September 2019, AMAG submitted an efficacy supplement, a type of PAS, to the FDA. (ECF 47 Ex. C at 83; *Id.* Ex. G at 1). This application proposed a change in the Makena labeling to "update all relevant sections of the label with the PROLONG study data in order to provide clinicians with a comprehensive understanding of all available safety and efficacy data." (ECF 47 Ex. C at 83).

After the PROLONG study was published in October 2019, the FDA convened a review committee to determine whether, in light of the study's results, there was still substantial

evidence that Makena was effective at reducing the risk of preterm birth. (Am. Compl. ¶ 129; ECF 47 Ex. B at 6).

On October 29, 2019, the FDA review committee found that the PROLONG study failed to confirm that Makena had clinical benefits, and that there was not substantial evidence to support its effectiveness. (Am. Compl. ¶ 130). The committee also voted to recommend that Makena should be removed from the market. (*Id.*).

AMAG, along with the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine, publicly opposed the committee's recommendation to withdraw Makena from the market. (*Id.* ¶ 131, 132). They argued that the efficacy data was mixed, and that the prior study had demonstrated effectiveness in high-risk pregnancies. (*Id.* ¶ 132).

Nevertheless, on October 5, 2020, the FDA proposed withdrawing Makena's approval. It offered AMAG an opportunity for a withdrawal hearing, which AMAG accepted. (*Id.* ¶ 137). Also on October 5, 2020, the FDA denied AMAG's proposed label change. (ECF 47 Ex. G). Specifically, in its Complete Response Letter, the FDA explained that approving a change to the labeling would be inappropriate because its committee "determined that Makena is not shown to be effective and is proposing to withdraw its approval" based on the results of the PROLONG study. Even so, the FDA that same day denied a citizen petition to withdraw Makena's approval immediately. (ECF 47 Ex. E).

In November 2020, Covis Holdings US, Inc. acquired AMAG and the rights to Makena. (*Id.* ¶ 134, 136; ECF 53 Ex. A at 2, 3). Covis Pharma GmbH, a Covis affiliate, then assumed the rights to Makena. (ECF 53 Ex. A at 3). In June 2021 Covis Pharma GmbH became Makena's FDA sponsor, and assumed responsibility for regulatory compliance and communication with the

FDA. (*Id.*; Am. Compl. ¶ 141). The Covis defendants contend that AMAG remained responsible for marketing Makena, even after the Covis acquisition. (ECF 53 Ex. A at 3).

In October 2022, the FDA held a hearing on whether it should withdraw approval for Makena. (*Id.* at 151). The complaint alleges that defendants advocated for maintaining approval, alongside several special-interest organizations that receive financial support from the Covis entities. (*Id.* ¶ 153).

On April 6, 2023, the FDA withdrew its approval of Makena. (*Id.* ¶ 154).

3. Makena Marketing and Promotion

According to the complaint, AMAG and the Covis defendants sought to maximize revenue from Makena between 2019 and 2023, despite knowing that the drug was not effective for its only approved indication. (*Id.* ¶ 14). The complaint alleges that defendants did so primarily through statements that Makena was effective at reducing the risk of pre-term birth. (*Id.* ¶ 64-67, 142, 148).

According to the complaint, between 2014 and its acquisition in 2020, AMAG relied on "an aggressive marketing campaign" to promote Makena. (*Id.* ¶ 61). It developed marketing materials that highlighted Makena's effectiveness to doctors and patients. (*Id.* ¶ 64-67). It facilitated endorsements from high-profile experts. (*Id.* ¶ 91-92). And it contributed substantially to interest and advocacy groups related to high-risk pregnancy and pre-term birth. (*Id.* ¶ 96, 99). AMAG also set up a system called "Makena Care Connection" to help coach patients and providers on how to communicate with insurers, in order to ensure coverage for individual Makena prescriptions. (*Id.* ¶ 81, 83-89). The complaint does not differentiate between AMAG's pre- and post-PROLONG marketing strategies.

The complaint further alleges that once Covis acquired AMAG, it engaged in further efforts to market Makena and delay withdrawal of its FDA approval. (*Id.* ¶ 139-150).

According to the complaint, in 2021, defendants commissioned a meta-analysis of synthetic progestin therapy, and, from 2021 to 2023, sponsored substantial advocacy and lobbying activity. (*Id.* ¶ 144, 148). The complaint alleges that these efforts were designed to undermine the FDA committee's recommendation to withdraw approval for Makena. (*Id.* ¶ 150).

According to the complaint, those marketing efforts "target[ed] third-party payors," like plaintiff. (*Id.* ¶ 68-79). Specifically, the complaint alleges that the pharmacy benefits managers ("PBMs") hired by third-party payors would not have recommended covering Makena on favorable terms if defendants had explained that the drug was not effective for its only approved use. (*Id.* ¶ 74-78).[2] The complaint does not allege any particular false or misleading statement a defendant made either to plaintiff or to OptumRx, plaintiff's PBM. (*Id.* ¶ 73). Instead, the complaint alleges that AMAG generally communicated to providers and the public that Makena was effective for its intended use, and that it was the only FDA-approved treatment for that intended use. (*Id.* ¶ 73-79). As a result, the complaint alleges, plaintiff and other similarly situated third-party payors were deceived into covering Makena. (*Id.* ¶ 76, 162-164). The complaint alleges that "plaintiff and members of the classes have paid millions of dollars for Makena that they would not have [otherwise] paid." (*Id.* ¶ 163). The complaint does not specifically allege that plaintiff in fact covered a single Makena prescription, let alone a prescription filled after the results of the PROLONG study were released.

C. Procedural Background

On October 27, 2023, plaintiff filed this action against AMAG and Covis Group S.à.r.l. On February 13, 2024, AMAG moved to dismiss the complaint for failure to state a claim, and

[2] PBMs are responsible for reviewing every prescription drug and recommending to the insurer whether to cover the drug, and (if so) on what terms. (Am. Compl. ¶ 71-73). These recommendations are periodically revisited. (*Id.* ¶ 72).

Covis Group S.à.r.l. moved to dismiss the complaint for lack of subject matter jurisdiction. In response, on March 29, 2024, plaintiff filed an amended complaint adding Covis Pharma GmbH as a defendant.

Defendants have moved under Fed. R. Civ. P. 12(b)(6) to dismiss the complaint in its entirety, contending that no count states a claim upon which relief can be granted. The Covis defendants have each also moved under Fed. R. Civ. P. 12(b)(2) to dismiss the claims against them for lack of personal jurisdiction. In response, plaintiff has moved for jurisdictional discovery.

II. Standard of Review

To survive a motion to dismiss under Rule 12(b)(6), the complaint must state a claim that is plausible on its face. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In other words, the "[f]actual allegations must be enough to raise a right to relief above the speculative level, . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 556). When determining whether a complaint satisfies that standard, a court must assume the truth of all well-pleaded facts and give the plaintiff the benefit of all reasonable inferences. *See Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007) (citing *Rogan v. Menino*, 175 F.3d 75, 77 (1st Cir. 1999)). Dismissal is appropriate if the complaint fails to set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." *Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008) (quoting *Centro Médico del Turabo, Inc. v. Feliciano de Melecio*, 406 F.3d 1, 6 (1st Cir. 2005)).

III. Analysis

A. Federal Claims

1. Count 1: RICO

Count 1 alleges a substantive civil RICO violation. RICO makes illegal any "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *See Feinstein v. Resolution Tr. Corp.*, 942 F.2d 34, 41 (1st Cir. 1991) (citing 18 U.S.C. § 1962). "Racketeering activity" is defined in 18 U.S.C. § 1961(1) to include a variety of predicate offenses, including, among other things, violations of the mail-fraud statute, 18 U.S.C. § 1341, and the wire-fraud statute, 18 U.S.C. § 1343.[3] The complaint alleges both wire- and mail-fraud predicates. (Am. Compl. ¶ 187).

a. Statutory Standing

The civil-suit provision of the RICO statute grants the right to sue to "[a]ny person injured in his business or property by reason of a violation of" the substantive provisions of the statute. 18 U.S.C. § 1964(c). Civil RICO claims "must be particularly scrutinized because of the relative ease with which a plaintiff may mold a RICO pattern from allegations that, upon closer scrutiny, do not support it." *Efron v. Embassy Suites (Puerto Rico), Inc.*, 223 F.3d 12, 20 (1st Cir. 2000). "[I]n cases alleging civil RICO violations, particular care is required to balance the liberality of the Civil Rules with the necessity of preventing abusive or vexatious treatment of defendants." *Miranda v. Ponce Fed. Bank*, 948 F.2d 41, 44 (1st Cir. 1991). "Civil RICO is an unusually potent weapon—the litigation equivalent of a thermonuclear device. The very pendency of a RICO suit can be stigmatizing and its consummation can be costly." *Id.*

[3] A "pattern of racketeering activity" means the commission of at least two related acts of racketeering activity during a period of ten years. 18 U.S.C. § 1961(5); *see In re Lupron Mktg. & Sales Pracs. Litig.*, 295 F. Supp. 2d 148, 164 (D. Mass. 2003) (citing *Schultz v. Rhode Island Hosp. Tr. Nat'l Bank, N.A.*, 94 F.3d 721, 731-32 (1st Cir. 1996)).

Accordingly, "courts should strive to flush out frivolous RICO allegations at an early stage of the litigation." *Figueroa Ruiz v. Alegria*, 896 F.2d 645, 650 (1st Cir. 1990).

To assert a civil RICO claim, a plaintiff must have standing under the RICO statute. As this Court has previously concluded, only direct purchasers have standing to bring RICO claims against their sellers. *See Humana, Inc. v. Biogen, Inc.*, 666 F. Supp. 3d 135, 154 (D. Mass. 2023), *aff'd*, 126 F.4th 94, 101 n.5 (1st Cir. 2025) ("We express no view of the district court's analysis" of the indirect-purchaser rule). This "indirect purchaser rule" is a "bright-line rule" borrowed from antitrust law. *Apple Inc. v. Pepper*, 139 S. Ct. 1514, 1520 (2019). It applies even when an indirect purchaser alleges that it ultimately bears all the costs associated with the statutory violation. *See Kansas v. Utilicorp United, Inc.*, 497 U.S. 199, 216 (1990). Nothing in the legal landscape has changed since this Court's decision in *Humana* to prevent the application of the indirect-purchaser rule in this case. *See Humana*, 126 F.4th at 101.

The complaint does not allege that plaintiff ever purchased Makena from AMAG or either Covis defendant. (Am. Compl. ¶¶ 68-79, 164-164). Nor can that fact be reasonably inferred from the allegations of the complaint; plaintiff is a fund that pays for health benefits for union members, not a direct purchaser of prescription drugs. (*Id.* ¶¶ 17, 68-69). Accordingly, plaintiff is an indirect purchaser of Makena and does not have standing to contest defendants' marketing practices under the RICO statute. *See Humana*, 666 F. Supp. 3d at 154 (D. Mass. 2023).

b. Fraudulent Labeling

The RICO claims are also independently inadequate. The complaint in essence alleges a scheme involving fraudulent drug labeling—in particular, a scheme based on the allegedly fraudulent representation in the label that Makena was effective for its approved use of reducing

the risk of preterm birth.[4] In substance, it alleges that AMAG should have amended the label to state that it was not effective for that purpose. (Am. Compl. ¶ 163; ECF 57 at 10). The complaint thus assumes that AMAG had the power to change the label, and that if it failed to do so, it could be subject to liability for fraud.

The principal problem arises from the fact that AMAG could not lawfully have made the changes that the complaint alleges were required to avoid liability under the federal fraud statutes. In particular, the complaint asserts that plaintiff's injuries arose because defendants did not disclose that "Makena lacked efficacy" and that "Makena was, in fact, not effective at preventing preterm birth." (Am. Compl. ¶ 163). Indeed, plaintiff argues that making the changes AMAG proposed in its efficacy supplement to the FDA—namely, "updat[ing] all relevant sections of the label with the PROLONG study data in order to provide clinicians with a comprehensive understanding of all available safety and efficacy data"—would have been insufficient to avoid federal fraud liability. (ECF 47 Ex. C at 83; ECF 57 at 10).

In general, a drug manufacturer "may distribute [its] drug without violating federal law as long as it uses [its] FDA-approved label." *In re Celexa & Lexapro*, 779 F.3d at 36. The FDCA prohibits drug labels from making a false or misleading statement and also establishes a system

[4] This matter, as noted, involves a claim that a new study showed that the drug was not effective for its approved use. It does not involve a claim that the FDA-approved drug was dangerous, or that the FDA had been defrauded into approving the label in the first instance. Those situations are governed by other provisions of federal law and FDA regulations.

Among other things, the Secretary of Health and Human Services "may suspend the approval of [a drug] immediately" if he "finds that there is an imminent hazard to the public health." 21 U.S.C. § 355(e). Furthermore, the suspension authority "shall not be delegated," even to another federal officer. *Id.*

Drug manufacturers are under an affirmative obligation to review all obtainable adverse drug experience information, and to promptly disclose them to the FDA. *See* 21 C.F.R. § 314.80(c). And when those adverse drug experiences are "both serious and unexpected," disclosure is required "as soon as possible but no later than 15 calendar days from initial receipt of the information." 21 C.F.R. § 314.80(c)(1)(i). In addition, drug manufacturers must disclose to the FDA any material changes to the information on which its approval was based, including safety and efficacy data. *See* 21 C.F.R. § 314.70.

of criminal and civil penalties to police the sale of misbranded drugs or drugs with fraudulent labels. *See* 21 U.S.C. §§ 331(c), 333(a), 352(a), (c).

It would be inconsistent with the FDCA regulatory regime to submit a drug manufacturer to liability under the federal mail- and wire-fraud statutes for (1) doing something that the FDA requires or (2) failing to do something that the FDA prohibits. Therefore, to state a claim for the mail- and wire-fraud RICO predicates, the complaint must, at a minimum, allege that it would have been legally possible to change Makena's label without prior FDA approval. That is essentially the same analysis used to determine FDA preemption of state law. *See Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 313–14 (2019) ("The underlying question for this type of impossibility pre-emption defense is whether federal law . . . prohibited the drug manufacturer from adding any . . . warnings to the drug label that would satisfy state law.").

As noted, a drug manufacturer can change its label in one of two ways: through the PAS process or the CBE process. Here, AMAG did utilize the PAS process, which eventually led to the withdrawal of approval of Makena by the FDA. Plaintiffs contend that AMAG should have instead used the CBE process to amend the label. (ECF 57 at 7-10).

It is true that a drug manufacturer can be found liable in tort for using an FDA-approved label if (1) the CBE process was available to make a change that would avoid liability, and (2) there is no "clear evidence" that the FDA would have rejected that change. *See Albrecht*, 587 U.S. at 312–13. "Clear evidence" requires that a drug manufacturer demonstrate that the FDA was "fully informed . . . of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning." *Id.* at 314; *see also In re Zofran (Ondansetron) Prods. Liab. Litig.*, 57 F.4th 327, 342 (1st Cir. 2023). The "clear evidence" standard is a matter of law

for the court to decide, rather than a matter of fact. *See Albrecht*, 587 U.S. at 316-18. And a drug manufacturer need not initiate a label change through the CBE process to establish "clear evidence" that the FDA would have rejected the proposed change. *See In re Zofran*, 57 F.4th at 342.

The CBE process is available to "reflect newly acquired information" that serves one of five enumerated purposes. 21 CFR §§ 314.70(c)(6), 201.57(a). One of those purposes is "delet[ing] false, misleading, or unsupported indications for use or claims of effectiveness." 21 C.F.R. § 314.70(c)(6)(iii)(D). However, the CBE process may not be used to make any "changes to the information required" to appear in all prescription-drug labeling. 21 C.F.R § 314.70(c); see 21 C.F.R. § 201.57(a). That information includes "[a] concise statement of each of the product's indications," which requires "stat[ing] that the drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a recognized disease or condition." 21 C.F.R. § 201.57(a)(6), (c)(2). The CBE process may be available to delete indications or claims of effectiveness in general, but it is not available to delete a drug's only approved indication, or to state that it is ineffective for that indicated use. Prior approval is required for such "major" changes. *See* 21 C.F.R. § 314.70(b)(2)(v)(C).

The CBE process was therefore not available to remove the statements that Makena was effective in reducing the risk of pre-term birth or to state that it was ineffective for that indication. Reducing the risk of pre-term birth was Makena's only approved indication. It could not be removed or disclaimed in a label conforming to FDA requirements. *See* 21 C.F.R. § 201.57(a)(6), (c)(2).

It is possible that the CBE process could have been used to add or account for the results

of the PROLONG study on the Makena label. But that cannot save the fraud predicates. First, the FDA rejected exactly those changes, which AMAG proposed in its PAS. (ECF 47 Ex. G at 1) ("[W]e cannot approve a supplement for labeling revisions to address the finding of [the PROLONG study] at this time."). Not only that, but it rejected the change for reasons that reflected precisely the justification for proposing the change in the first place—that is, the results of the PROLONG study indicated that Makena was ineffective. (*Id.*; ECF 47 Ex. D). The FDA's response letter, and its concurrent notice of a proposal to withdraw Makena's approval, therefore establish "clear evidence" that the changes available to be made through the CBE process would have been rejected.[5]

And it is no answer to say that AMAG should have simply stopped selling the product, even though its label had been approved by the FDA. For that theory to be viable, plaintiff would have to be permitted to argue that the federal mail- and wire-fraud statutes effectively trump the requirements of the FDA, and that the threat of a civil lawsuit can accomplish what the FDA amendment processes cannot. It is noteworthy that under the preemption analysis, a drug manufacturer cannot be held liable for using an FDA-approved label if there was no alternative way to market the drug consistent with state law. *Bartlett*, 570 U.S. at 475. In other words, any claim based on a failure to stop selling the product with the approved label is squarely preempted. *Id.* ("The Court of Appeals' solution—that Mutual should simply have pulled

[5] Another court, facing the same issue in a related case, found otherwise. That court reasoned that "[b]ecause AMAG: (i) did not submit a supplement to avail itself of the CBE exception; (ii) proffered nothing to show that it attempted to utilize the CBE exception; and (iii) opted for a sNDA instead of the CBE exception," the FDA's Complete Response Letter was not clear evidence that the FDA would have rejected its proposed label change. *Maher v. AMAG Pharms., Inc.*, 2024 WL 1376685, at *12 (D.N.J. Mar. 28, 2024).

That reasoning is inconsistent with First Circuit precedent declining to require actual submission of a CBE supplement to claim a preemption defense. *See In re Zofran*, 57 F.4th at 342. And it relies on a false distinction between a CBE supplement, which is a type of sNDA, and the PAS sNDA AMAG submitted (which is also an sNDA). See 21 C.F.R. § 314.70. Both mechanisms are available to propose a label change, and the FDA's rejection of AMAG's sNDA was a rejection of its proposed change. See (ECF 47 Ex. G).

sulindac from the market in order to comply with both state and federal law—is no solution. Rather, adopting the Court of Appeals' stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in this Court's pre-emption case law. Accordingly, we hold that state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law [.]").

In summary, defendants could not legally have revised Makena's label to state that it was not effective for its only indicated use without obtaining prior approval. And the uncontested record reflects clear evidence that the FDA would have rejected any more moderate revisions designed to account for the results of the PROLONG study. Accordingly, the mail- and wire-fraud predicates of the complaint's RICO claim fail as a matter of law.

c. Pleading Fraud with Particularity

The complaint also fails to plead sufficient facts to establish any predicate fraud offense with the particularity required by Fed. R. Civ. P. 9(b). Even if the fraud claims could be based on statements required by the FDA, the complaint does not "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Under Rule 9(b), although intent may be alleged in general terms, the complaint must specifically allege the content of each fraudulent statement, why it is false or misleading, who made the statement to whom, and when. *See id.*; *Humana*, 126 F.4th at 104.

The complaint fails at each turn. It identifies several instances of marketing claims that indicate that Makena is effective at reducing the risk of pre-term birth. (Am. Compl. ¶ 64-67, 73-79). However, it does not allege that plaintiff or its agents relied on any of these statements. It does not allege the dates these statements were publicized, or to whom. It does not allege that any of its beneficiaries sought out or obtained Makena prescriptions in reliance on any of these statements. It does not allege that any of the relevant providers prescribed Makena in reliance on

any of these statements. In fact, it does not allege that it covered a single Makena prescription at all.

Accordingly, at a minimum, the complaint fails to state the fraud predicates of the RICO claim with sufficient particularity. The RICO claim will therefore be dismissed for failure to state a claim.

2. Count 2: RICO Conspiracy

Because the complaint fails to plead a substantive RICO claim, its claim for conspiracy to commit a RICO offense must also be dismissed. *See Efron*, 223 F.3d at 21 (holding that if the pleadings fail to state a substantive RICO claim, then the conspiracy claim also fails); *Langan v. Smith*, 312 F. Supp. 3d 201, 205 (D. Mass. 2018) (same).

B. State-Law Claims

In addition to the federal-law claims, the complaint alleges 41 state-law counts arising under the laws of 36 states.[6] None of those counts state a claim upon which relief can be granted.

The state law claims, aside from the claim for "common law unjust enrichment," all stem from defendants' purported fraudulent statements or purported attempts to delay the withdrawal of Makena's FDA approval. (Am. Compl. ¶ 228-1111). But state law cannot subject a company to liability for conduct required by federal law, because, under the Supremacy Clause, "state laws that conflict with federal law are without effect." *See Bartlett*, 570 at 479–80.

To the extent that the state-law claims depend on defendants' failure to disclose that Makena was not effective for its only approved indication, they are preempted. This is true for

[6] The Court interprets liberally the allegation that plaintiff and class members "have paid millions of dollars for Makena that they would not have paid" to allege an amount in controversy over $5,000,000. Thus, because there is minimal diversity between the parties, the Court exercises mandatory jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2).

precisely the same reasons that the labeling and marketing materials plaintiffs contest cannot subject them to federal fraud liability: defendants could not lawfully have made the changes plaintiff demands.

And to the extent that those claims depend on defendants' attempts to delay FDA approval, primarily by seeking a hearing on the FDA's proposal to withdraw approval, those claims are preempted as well. A party that holds the rights to a drug has a statutory right to a hearing on any agency recommendation to withdraw approval for the drug. *See* 21 U.S.C. § 355(e); 21 C.F.R. § 314.530. Taking advantage of that statutory right cannot subject the party to liability under state consumer-protection laws.

The common-law unjust-enrichment claim relies on defendants accruing profits from their otherwise unlawful conduct. (Am. Compl. ¶ 215-227). Because the rest of the complaint fails to allege any kind of unlawful conduct, this claim, too, fails as a matter of law.

C. Motion to Dismiss for Lack of Personal Jurisdiction

Because all claims will be dismissed for failure to state a claim upon which relief can be granted, the Court need not reach the motions to dismiss for lack of personal jurisdiction. *See Estados Unidos Mexicanos v. Smith & Wesson Brands, Inc.*, 633 F. Supp. 3d 425, 438 (D. Mass. 2022), *rev'd on other grounds*, 91 F.4th 511 (1st Cir. 2024), *certiorari granted*, 145 S.Ct. 116 (2024); *Johnson v. Andrews*, 1994 WL 455013, at *4 (D. Mass. Aug. 17, 1994); *see also Chevron Corp. v. Naranjo*, 667 F.3d 232, 247 (2d Cir. 2012) ("[I]n cases such as this one with multiple defendants—over some of whom the court indisputably has personal jurisdiction—in which all defendants collectively challenge the legal sufficiency of the plaintiff's cause of action, we may address first the facial challenge to the underlying cause of action and, if we dismiss the claim in its entirety, decline to address the personal jurisdictional claims made by some defendants."); *In re Vitamins Antitrust Litig.*, 2001 WL 849928, at *11 (D.D.C. Apr. 11, 2001); 4

Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 1067.6 (4th ed.) (A court can "resolv[e] the suit on the merits when they clearly must be decided in favor of the party challenging [personal] jurisdiction, thereby obviating any need to decide the [jurisdictional] question.").

Plaintiff's motion to take jurisdictional discovery will be dismissed as moot.

IV. Conclusion

For the foregoing reasons, the motions of defendants AMAG Pharmaceuticals, Inc., Covis Group S.À.R.L, and Covis Pharma GmbH to dismiss under Fed. R. Civ. P. 12(b)(6) are GRANTED. The motions of defendants Covis Group S.à.r.l. and Covis Pharma GmbH to dismiss for lack of personal jurisdiction are DENIED as moot. Plaintiff's motion for leave to conduct jurisdictional discovery is DENIED as moot.

So Ordered.

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
Chief Judge, United States District Court

Dated: March 12, 2025